

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-32 are now pending. Claims 10, 11, 12, 26 and 27 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply to place the claims in better condition for examination and to correct typographical errors.

II. RESPONSE TO RESTRICTION REQUIREMENT

The March 24, 2006 Office Action required restriction from among:

- | | |
|-----------|---|
| Group I | Claims 1-25, drawn to a method for releasing a soluble or membrane associated intracellular protein of interest (POI) from a cell by using a quaternary ammonium compound, classified in class 530, subclass 412; |
| Group II | Claims 26 and 28, drawn to a method for screening for mutated cells or transformed cells by using a membrane extracting composition, classified in class 435, subclass 7.23; |
| Group III | Claim 27, drawn to a membrane extracting composition to release a POI, classified in class 514, subclass 789; and, |
| Group IV | Claims 29-33, drawn to a POI including HOX enzyme produced by the method of releasing POI, classified in class 435, subclass 183. |

Applicants hereby elect, with traverse, the claims of Group I.

Furthermore, the Office Action required an election of one of the following species:

- A. IL-1ra enzyme;
- B. Glucan lyase enzyme; or,
- C. HOX enzyme.

Applicants hereby elect, with traverse, the species HOX enzyme. Applicants respectfully submit that claims 1-17 and 22-32 read on this election.

In addition, the Office Action required that a single species of quaternary ammonium compound releasing proteins. In response, Applicants hereby elect, with traverse, Lauroyl Trimethyl Ammonium Bromide (LTAB). Applicants respectfully submit that all of claims 1-32 read on this election.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action states that the claims of Groups III and IV are unrelated and that the claims of Groups I and III are related as product and process of use. The Office Action alleges that because the claims of Group III can be used for the “materially different process of extracting unrelated proteins,” the Groups of claims are therefore distinct each from the other. Applicants respectfully disagree. The fact that the claims of Group III can be used to extract unrelated proteins is not sufficient to render the Groups distinct as the claims of Group III would be used in essentially the same manner, regardless of what protein was being extracted.

The Office Action also states that the claims of Group IV are unrelated to the claims of Groups I-II as they have different modes of operation and different functions. Applicants respectfully submit that the claims of Groups IV and I-II are related as the protein of interest claimed in Group IV is necessarily interrelated to the claims of Groups I and II, both of which relate to the release of such a protein of interest. Furthermore, the Office Action states that the claims of Groups I and II are unrelated because “they comprise unrelated steps, use different products and produce different effects.” It is respectfully submitted that this statements neglects to take into consideration the underlying similarities between the Groups, specifically that both methods involve the release of an intracellular protein of interest.

The Office Action also alleges that the proteins IL-1ra enzyme, Glucan lyase enzyme and HOX enzyme are unrelated and patentably distinct. Applicants respectfully disagree. Initially, the three proteins share fundamental similarities, such that the separation of the three into separate groups is unduly burdensome on Applicants. And, Applicants respectfully submit that the “restriction requirement” as applied to the proteins IL-1ra enzyme, Glucan lyase enzyme and HOX enzyme is improper, and should have properly been drawn as a further election of species if an election between the enzymes was desired.

Furthermore, for a restriction requirement to be proper, it must satisfy both of the above elements. Accordingly, the present restriction requirement is improper and must be withdrawn because the Office Action only alleges that the inventions are distinct, as described above. The Office Action provides no showing that search and examination of the claims would be an undue and serious burden. Indeed, Groups II-IV encompass only eight claims in total, Groups II and III accounting for three of those claims. Accordingly, the search and examination of Groups II and III along with the claims of Group I would only add three additional claims to the total number of claims to be searched, and there is no required showing in the Office Action that such an addition of three claims would result in an undue burden. Therefore, the restriction requirement is improper because it does not satisfy both requirements for restriction and should be withdrawn.

Turning now to the species election, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a), which states that “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

The Office Action states that the election of species is required because the application “contains claims directed to ... patentably distinct species,” of quaternary ammonium compounds. However, the Office Action does not provide any allegations or statements to support the conclusory statement that the species are patentably distinct. Indeed, the species recited are related through their identification as all being quaternary ammonium compounds useful in the release of intracellular proteins of interest. Accordingly, there is a disclosed, cohesive relationship between the species as provided in the specification, as was inherently

acknowledged by the Examiner in the format in which the species election was required. For example, Applicants were required to select a single “quaternary ammonium compound”, thereby demonstrating that the Examiner acknowledged that the “species” from which election was required are all related to each other as being “quaternary ammonium compounds”. Simply, this is not an instance where Applicants are being requested to select from a species that includes different organisms or other entities wherein specific differences exist that would hinder the Examiner’s ability to search and examine the application. Rather, the present Office Action asks the Applicant to select individual examples of those components used in the invention, such that the ultimate result would be an invention with severely limited function.

In view of the remarks herein, enforcing the present restriction requirement and election of species would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction and election have not been shown to be proper, especially in view of the lack of assertions in the Office Action as to the requisite showing of serious burden, in contrast to the requirements of MPEP 803.04. Indeed, the search and examination of each Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction and election of species.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the restriction requirement or modification thereof.

CONCLUSION

Reconsideration and withdrawal of the restriction requirement and election of species,
and an early and favorable examination on the merits is respectfully requested in view of the
remarks herein.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: Thomas J. Kowalski by Angela M. Collison
Thomas J. Kowalski
Reg. No. 32,147
Angela M. Collison
Reg. No. 51,107
Tel. (212) 588-0800
Fax (212) 588-0500